REMARKS

Status of the Claims

Claims 1-28, 32, 35-74, 78, 81-90 are pending in the application, claims 29-31, 33, 34, 75-77, 79, 80 having been canceled herein and claims 89 and 90 having been added. Claims 2, 17, 32, 35-74, 78, 81-85 are withdrawn from consideration. Claims 1, 3-16, 18-28 and 86-88 are under examination.

Support for new claims 89 and 90 can be found, for example, in original claims 1, 20 and 24 and paragraphs [0079] and [0080] of the specification. No new matter is added.

Withdrawn Rejection of Claims 1, 3-16, 18, 19 and 22-28 under 35 U.S.C. §103(a)

The rejection of claims 1, 3-16, 18, 19 and 22-28 under 35 U.S.C. §103(a) as being unpatentable over O'Hagan et al., WO 98/33487 (O'Hagan) in view of Hawkins et al., US 6,290,973 (Hawkins) is noted with appreciation.

Withdrawn Rejection of Claims 20 and 21 under 35 U.S.C. §103(a)

The rejection of claims 20 and 21 under 35 U.S.C. §103(a) as being unpatentable over O'Hagan and Hawkins in view of Muttilainen et al., *Microbial Pathogenesis*, 1995, 18:423-436 (Muttilainen) and Cox et al., *Vaccine*, 1997 (Cox) is noted with appreciation.

Claim Rejection under 35 U.S.C. 112, first paragraph (enablement)

Claims 1, 3-16, 18-28 and 86-88 are rejected under 35 U.S.C. 112, first paragraph, because the specification alleged does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

According to the Office Action, the specification, while being enabling for an immunogenic composition comprising those components in the immunogenic compositions set forth in Tables 2 and 3A-3C, does not reasonably provide enablement for an immunogenic composition comprising any combination of possible components as set forth in the claims.

With regard to enablement, see for example, MPEP 2164.01, a pertinent portion thereof reads as follows:

> Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).... See also *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.") A patent need not teach, and preferably omits, what is well known in the art.…

Thus, the disclosure in the patent application, coupled with information known in the art, must contain sufficient information to enable one skilled in the pertinent art to *make and use* the claimed invention without undue experimentation.

With regard to the description regarding *how to make* the claimed invention, all presently pending claims under examination concern an immunogenic composition that comprises: (a) water; (b) a polymer microparticle; (c) an antigen adsorbed to the microparticle; and (d) a synthetic phospholipid compound. Disclosed throughout the present specification, including the working examples, are methods of making the claimed immunogenic compositions. Regarding phospholipids see, for instance, paragraphs [0064] to [0081] and the references set forth therein; regarding antigens see, for instance, paragraphs [0082] to [0092] and the references set forth therein; regarding microparticles, including how to form them and how to associate species such as antigens and phospholipids with them (e.g., adsorption, entrapment, etc.) see, for instance, paragraphs [0120] to [0137] and the references set forth therein. See also Examples 1-3.

Accordingly, it is respectfully submitted that, based on the present disclosure, one skilled in the art could readily make the claimed invention without undue experimentation, indeed, with little to no experimentation.

With regard to the description as to *how to use* the claimed invention, the specification describes numerous ways of administering the immunogenic compositions of the claimed invention, including various modes of injection, nasal administration, mucosal administration, intraocular administration, rectal administration, vaginal administration, oral administration,

pulmonary administration, and so forth. See, e.g., paragraphs [0145] to [00149] and the references set forth therein, as well as Example 3.

Concerning the immunogenic aspect of immunogenic composition claims 1, 3-16, 18-28 and 86-88 under examination, as defined in the present specification, by an "antigen" is meant a molecule that contains one or more epitopes capable of stimulating a host's immune system. Antigens defined thusly are readily available and well-known in the art. See, e.g., paragraphs [0082] to [0092] and the references set forth therein. Because antigens are, by definition, capable of stimulating an immune response in a host, composition claims 1, 3-16, 18-28 and 86-88 under examination are clearly immunogenic. In other words, even assuming solely for the sake of argument that the claimed combination of adjuvants (i.e., polymer microparticle and synthetic phospholipid) were to have no impact on the immunogenicity of the composition, the composition would nonetheless stimulate an immune response because the antigen in the composition, by definition, will contain one or more epitopes capable of stimulating the host's immune system.

It is recognized, however, that the art of record attests to the unpredictability associated with the immunological response that arises upon administration of immunogenic compositions containing adjuvants to a host animal, in particular, there is unpredictability regarding the specific contours of the immunological response. For example, as noted in the Office Action, questions such as the following may arise: Does the adjuvant induce cell mediated (Thl) immunity, humoral (Th2) immunity, or a balance of Thl and Th2? Which Ig isotypes dominate? Which cytokines are induced? Are CD4+ T-helper cells or CD8+ cytotoxic T-lymphocytes induced?

In this regard, several claims pending at the time of the Office Action specify the particular outcome that is achieved upon administration of the claimed immunogenic compositions to a host animal, specifically, method claims 29 and 75 (drawn to methods wherein a therapeutic outcome is achieved in a host animal), method claims 30 and 76 (drawn to methods wherein a host animal having a pathogenic organism infection or tumor is treated), method claims 31 and 77 (drawn to methods wherein a host animal is immunized against a tumor or infection by a pathogenic organism), method claims 33 and 79 (drawn to methods wherein a

humoral immune response is stimulated in a host animal), and method claims 34 and 80 (drawn to methods wherein a cellular immune response is stimulated in a host animal).[1]

While Applicant believes that one skilled in the art would in fact be able to make and use the invention as defined in these method claims without *undue* experimentation,[2] due to the art-described unpredictability associated with the particulars of the immunological response arising from administration of immunogenic compositions containing adjuvants to a host animals, the issue of enablement is perhaps less straightforward for these claims this it is for the other claims.

Consequently, claims 29-31, 33, 34, 75-77, 79 and 80, which set forth details regarding the particular outcome that is achieved upon administration of the claimed immunogenic compositions to a host animal, have been canceled herein in order to expedite allowance of the present application. Applicant, however, reserves the right to pursue such claims in the future.

Moreover, it is also respectfully submitted that the claims are further enabled based on the fact that the two adjuvants are claimed by class (i.e., polymer microparticle and a synthetic phospholipid compound). Each adjuvant within a respective class would be reasonably expected to behave in a fashion analogous to other adjuvants in the same class. Since the inventors have shown that an exemplary adjuvant from each class can be combined, one of ordinary skill in the art would be expected to be able to combine other adjuvants from the same two classes without undue experimentation.

In view of the above, withdrawal of the rejection of claims 1, 3-16, 18-28 and 86-88 under 35 USC 112, first paragraph, is requested.

CONCLUSION

Applicant submits that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

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[1] Claims 32 and 78 (and claims depending therefrom), are directed to a method of stimulating an immune response and thus do not specify the specific nature of the immune response that is developed upon administration of the claimed immunogenic compositions to a host animal.

[2] Indeed, the quantity of experimentation required to make and use the invention may be considerable and may stretch over an extended period (see MPEP 2164.06 and the cases cited therein).

FEES

The Office is authorized to charge any fees that may be due and owing as a result of this Response to deposit account number 50-1047.

Respectfully submitted,

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